Applicants respectfully submit that the claims in Group I, II & III are all directed to compositions or methods for tissue bulking that require biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microspheres and a biocompatible carrier. Thus, this specific feature is present in all the claims. Therefore, even if the Applicants were to elect one of the groups, the required search would necessarily encompass the subject matter of the other groups.

As stated in § 803 of the *Manual of Patent Examining Procedures* ("*MPEP*") (August, 2001):

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions (emphasis added).

Thus, all of the subject matter in Groups I II & III should be examined together. Moreover, even if the subject matter of these groups were distinct inventions, it would not be a "serious burden" on the Examiner to search these groups in this application. Applicants, therefore, respectfully request that the restriction of the claims be reconsidered and withdrawn.

Prior to addressing the election of species also requested by the Examiner, Applicants respectfully point out that characterization of the claimed invention, in particular those made on pages 3-4 of the Office Action, are incorrect. For example, the Examiner alleges that the tissue bulking composition comprises "a biocompatible carrier, a microsphere, and a cross-linker." This is incorrect. While the claimed injectable composition does comprise particular microspheres and a biocompatible carrier, as recited in claim 1, a cross-linker is only a component of some, but not all, polymers that the claimed microspheres comprise, as recited in claim 13. The Examiner is also erroneous in characterizing that "possible biocompatible carriers include saline, PBS, alcohol solutions, acrylamino-e-propion-amido-3-triiodo-2,4,6-benzoic acid, sodium, potassium, calcium, magnesium, iron, zinc, and ammonium." As described in the specification at page 17, line 16 to page 19, line 27, and recited in claims 4-10, the biocompatible carriers of the present invention can be an emulsion, an organic or non-aqueous solution, or an aqueous based or hydro-organic solution. In a different categorization, the biocompatible carriers of the present invention may also comprise salts selected from the listed group of cations in a specific amount, as recited in claims 8 and 9. Further, acrylamino-e-propion-amido-3-triiodo-2,4,6-

benzoic acid is a specific biocompatible carrier that can be used for the invention. Thus, it is incorrect to group these different characterizations of the biocompatible carrier together and require that one be elected.

As the Examiner is well aware, "[c]laims to be restricted to different species must be mutually exclusive." *Manual of Patent Examining Procedures* § 806.04(f) (August, 2001) (*"MPEP"*) (emphasis added). "The general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first." *Id.* (emphasis added).

The specific types of biocompatible carriers recited by claims 4-10, which belong to different categories of biocompatible solutions, are all biocompatible carriers suitable for the claimed injectable composition. There is no suggestion, however, that any of the solutions is not included within the group of biocompatible carriers suitable for the injectable composition, as recited by claim 1. Furthermore, because the Examiner's characterization of the biocompatible carriers is erroneous, as discussed herein, it is impossible for Applicants to elect one of the alleged species defined by the Examiner and properly cover what has been discovered by the present invention. It is therefore respectfully submitted that the biocompatible carriers listed on page 3 of the Office Action are not separate species, and that the requirement for electing one of them should be reconsidered and withdrawn.

Similarly, the polymers recited in claim 12 all share the feature that microspheres comprising one or more of the polymers are, or can be made to be, biocompatible, swellable, hydrophilic, non-toxic and substantially spherical. Applicants therefore respectfully submit that the division of these polymers into separate species is also inappropriate and should be withdrawn.

As to the Examiner's requirement that a single cross-linker is elected, Applicants respectfully submit that the requirement not only is based on an erroneous characterization of the claimed invention, as discussed herein, but also inappropriately restrict the claimed invention, since a cross-linker is only required by some, but not all, polymers that a microsphere of the present invention comprises. The requirement, therefore, should be reconsidered and withdrawn.

For these reasons, it is further submitted that a search of the inventions recited by the pending claims would encompass each of the alleged species discussed on pages 3-4 of the Office Action. This alone is reason enough for the required election of species to be withdrawn. *See, e.g.*, *MPEP* § 806.04(a).

To order to be fully responsive, Applicants elect, with traverse, sodium acrylate polymer as a required component of the microspheres, saline as the biocompatible carrier, and tetraethylene glycol diacrylate as the cross-linker.

In conclusion, Applicants respectfully submit that the restriction and election of species requirements set forth in the Office Action are inappropriate and should be withdrawn.

No fee is believed to be due for this response, except for the fee required for the Petition for Extension of Time submitted herewith. Should any fees be required please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date November 18, 2002

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